K010933

10. 510(k) Summary

JAN 0 8 2002

1. **Submitter:** Alltracel Pharma Ltd.
10 Church Place
Sallynoggin, Co, Dublin
Republic of Ireland

2. **Contact Person:** Dr. Ivan Santar, Scientific Director & QA Officer
Phone: 011 353 1 2352162 or
011 420 504 410154

3. **Device Name:** Seal-On™ Hemostatic Powder Spray

4. **Classification Name:** Liquid Bandage (21 CFR 880.5090)

5. **Predicate Devices:** Tegagen Alginate Dressing (K980989)
Dermaphylyx Calcium Alginate Wound Dressing (K991608)
Medtrade Products Alginate Island Dressing (K000487)

6. **Device Description and Intended Use:**

Seal-On™ is a hemostatic powder spray containing Microdispersed Oxidized Cellulose in an aerosol form and is indicated for OTC use in the topical control of bleeding from minor cuts and abrasions of the skin surface.

7. **Substantial Equivalence:**

The intended use of Seal-On™ is consistent with that for the cited predicate devices. It differs from the predicate devices in that its active component is microdispersed oxidized cellulose that, similar to the predicate devices, is derived from a plant source. Oxidized cellulose has very low systemic toxicity and virtually no antigenicity or immunogenicity and has a long history of safe and effective use as an absorbable hemostatic agent during surgical procedures where it is partially or fully absorbed. The intended use of Seal-On™ results in extremely minimal absorption at best. Appropriate biocompatibility test results were included in the premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 8 2002

Alltracel Pharma Ltd.
c/o Mr. Charles H. Kyper
Kyper and Associates
103 Nolen Lane
Chapel Hill, North Carolina 27516

Re: K010933/S3
Seal-On™ Hemostatic Powder Spray
Regulatory Class: unclassified
Product Code: FRO
Dated: November 22, 2001
Received: November 26, 2001

Dear Mr. Kyper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010933

3. STATEMENT OF INTENDED USE

Seal-On™ Topical Hemostatic Spray is intended to be used for topical control of bleeding from minor cuts and abrasions of the skin surface.

NPA for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010933